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EXAMINER	
ORWIG, KEVIN S	

ART UNIT	PAPER NUMBER
4161	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,215	TOYODA ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *6,7,13 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 8-12, 14-16, and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/27/06, 3/8/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-18 are currently pending. Claims 1-12, 14-16 and 18 are the subject of this Office Action. This is the first Office Action on the merits of the claims. Non-elected claims 6, 7, 13, and 17 are withdrawn from consideration.

Election/Restrictions

Applicant's election of Group I (claims 1-12, 14-16 and 18) in the reply filed on Jul. 14, 2008 is acknowledged. In response to applicant's election, Group II (claims 13 and 17) are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants have further elected the following species: sucrose (claims 9 and 10) and hydroxypropyl cellulose (claims 3 and 4). Claims 6 and 7 recite a natural polymeric compound (claim 6), wherein the natural polymeric compound is alginate (claim 7). Hydroxypropyl cellulose is manufactured and is not a natural polymeric compound. Thus, in response to the species election, claims 6 and 7 have been withdrawn as being drawn to nonelected species. Applicants have elected Group I with traverse.

The traversal is on the ground(s) that anticipation of the claimed invention cannot provide a basis for a restriction requirement and that there is no serious search burden. This traversal is not found to be persuasive because there are two inventions, one drawn to a dry syrup preparation, and one drawn to a method. Group I is drawn to a different statutory category of invention (a composition of matter) than Group II, which is

drawn to a method. While related by the claimed dry syrup preparation, the two inventions are not so closely related as to depend absolutely upon one another and are therefore patentably distinct.

The instant application is a 371 national stage application of PCT/JP04/11333. Thus, international restriction practice applies under 35 U.S.C. 121 and 372.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

PCT Rule 13.2 states that the unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, **Part 1(a)**, indicates that the application should relate to only one invention, or if there is more than one invention, inclusion is permitted if they are so linked to form a single general inventive concept.

Annex B **Part 1(b)**, indicates that "special technical features" means those technical features that as a whole define a contribution over the prior art.

As pointed out in the restriction requirement of May 1, 2008, the formulation of Group I is known in the prior art (i.e. anticipated). As such, this element cannot be considered novel, and the Groups do not share a common special technical feature and are subject to restriction. Furthermore, a search for a preparation may not reveal prior art for a method for making and/or using that preparation and vice versa. Thus, the restriction requirement is still deemed proper and is therefore made FINAL.

Priority

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be Aug. 6, 2004, the filing date of PCT application PCT/JP04/11333 to which the instant national stage 371 application claims priority. Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the Japanese application was filed with the USPTO on Jan. 27, 2006.

Information Disclosure Statement

References lined-through on the information disclosure statement(s) were not considered because they were not provided or were not provided in English.

Abstract

The abstract is objected to since it fails to appropriately describe the disclosed invention. In particular, an "argininic acid" salt is not disclosed in the specification and does not appear to be a component of the invention in any embodiment. Thus, the current abstract is inaccurate.

Specification

Numerous instances of improper grammar and/or non-idiomatic English have been noted throughout the specification. It is requested that applicant review the specification and correct the language where appropriate to provide a clearer and easily understandable disclosure. In addition to various grammatical mistakes, non-standard

terms have been used, for instance the phrase "thrown into water" (paragraphs [0007], [0009], [0013]-[0015], [0048], and [0049]) is not commonly used and is awkward.

Claim Objections

Claims 1-5, 8-12, 14-16, and 18 are objected to because of the following informalities: the claims should begin with an article. For example, independent claims 1, 14, 15, and 18 should start with "A" and the dependent claims should start with "The".

Claim 5 is objected to because of the following informalities: the word "a" should be inserted before the phrase "2% aqueous solution".

Claim 8 is objected to because of the following informalities: the word "a" should be inserted before the word "saccharide".

Claim 12 is objected to because of the following informalities: the word "sedimantation" should be "sedimentation".

Claims 12 and 16 are objected to because of the following informalities: the word "upset" and the phrase "turned back" are not typically used in the art and should be replaced by more precise and commonly used terminology such as the term "inverted".

Appropriate correction is required.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. The term "sedimentation" in element (i) of these claims is unclear and renders the claims indefinite. While there is a brief discussion of sedimentation in paragraph [0048] of the instant specification, this discussion does not fully clarify the term. Specifically, it appears that applicants intended to measure the time it takes for some amount of the preparation to sink below the water surface. However, how much material must sink below the water surface is not discussed. Thus, the term "sedimentation" could refer to any or all of the material and amounts to a subjective or relative judgment.

Additionally, the term "cloudy" is a relative term that renders the claims indefinite. What appears cloudy to one person of ordinary skill in the art may not appear cloudy to another. This term is not defined by the claim and the specification does not provide a sufficient standard for ascertaining the requisite degree that constitutes a "cloudy" solution. For these reasons, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and the claims are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8-10, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen *et al.* (U.S. Patent Application Publication No. 2003/0077297; Published Apr. 24, 2003) (hereinafter Chen *et al.*).

1. It is noted that "dry syrup preparations" are defined as "preparations which are dissolved or suspended before use" in the instant specification (paragraph [0003]). This definition is extremely broad and does not limit the physical properties of the claimed dry syrup preparations. Thus, the dry syrup preparations, as defined herein, can be any preparation able to be dissolved or suspended prior to use.

2. Chen *et al.* disclose formulations in which active agents are suspended in a carrier vehicle (abstract; paragraph [0012]). In these formulations, a first portion of the active agent is in the form of solid particles which are suspended in the vehicle and a second portion of the active agent is solubilized (i.e. dissolved) in the vehicle (paragraph [0012]). Thus, the active agents of Chen *et al.* are dissolved or suspended before use and represent dry syrup preparations as defined in the instant specification. Chen *et al.* teach the use of antihistamines including loratadine in their formulations (paragraphs [0058] and [0071]). Chen *et al.* also teach the use of binders and stabilizing agents such as hydroxypropyl cellulose (paragraph [0275]). These formulations are highly water-dispersible (paragraph [0018]) and therefore provide uniform dispersion when added to water. Chen *et al.* also teach the use of sucrose (i.e. a sugar) (paragraph [0223]). Thus, Chen *et al.* reads on instant claims 1-4, 9, 10, 14, and 15.

3. It is noted that claim 15 is a product-by-process type claim. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The MPEP states: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of

production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP § 2113.

4. Claim 15 is drawn to a dispersion provided by "throwing the dry syrup preparation of claim 1 into water and stirring". The substance and structure of the claimed dispersion is not affected by this limitation, which merely reflects one version of a process that could be used to make the product. If the product in this claim is the same as or obvious from a *product* of the prior art, the claim is unpatentable. The dispersion is clearly disclosed in the prior art (see paragraphs 1 and 2 above), thus claim 15 is rejected as unpatentable over Chen *et al.*

5. Chen *et al.* also teach that the sugar component may be a saccharide (paragraphs [0172]), reading on instant claim 8.

Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Compton *et al.* (U.S. Patent Application Publication No. 2003/0059471; Published Mar. 27, 2003) (hereinafter Compton *et al.*).

6. Compton *et al.* disclose flakes containing drugs (abstract; paragraphs [0012] and [0013]). These flakes are intended to be used as part of various administration forms, including suspensions as in syrups and elixirs (paragraph [0315]). In this case, the flakes are suspended in aqueous solutions before use and represent dry syrup preparations as defined in the instant specification. Compton *et al.* teach the use of antihistaminic agents including loratadine in their formulations (paragraphs [0147], line 13 and [0292], page 24, column 2, middle of the page). Compton *et al.* also teach the

use of normal pharmaceutical excipients such as binders (paragraphs [0032] and [0304]) and teach the use of hydroxypropyl cellulose (paragraphs [0055] and [0056]). The compositions taught by Compton *et al.* can be prepared by uniformly associating the compounds with a liquid carrier (i.e. water), thus providing a uniform dispersion upon mixing with the liquid carrier (paragraph [0314]). Compton *et al.* also teach the use of sugars including sucrose (paragraph [0058]). Compton *et al.* do not disclose the use of surfactants or defoaming agents. Thus, Compton *et al.* reads on instant claims 1 and 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen *et al.* in view of Shimizu *et al.* (U.S. Patent No. 5,824,339; Issued Oct. 20, 1998) (hereinafter Shimizu *et al.*).

8. Chen *et al.* teach the dry syrup preparation of instant claims 1-4 as discussed above in paragraphs 1 and 2. Chen *et al.* are silent as to the type of hydroxypropyl cellulose used.

9. Shimizu *et al.* disclose compositions comprising solid forms of active substances which are useful in preparing uniform suspensions (abstract; column 3, lines 18-21). Since the active agent in these compositions is uniformly suspended, the active agents of Shimizu *et al.* are suspended before use and represent dry syrup preparations as defined in the instant specification. Shimizu *et al.* teach the use of additives such as binders (column 6, line 40) and teach the use of water-soluble polymers including hydroxypropyl cellulose (HPC) (abstract; column 4, line 40). In particular, Shimizu *et al.* teach the use of HPC of the SSL type (HPC-SSL) which has a different level of hydroxypropoxy substitution and different viscosity modifying properties than lower-substituted HPC (column 4, lines 55-65; examples 1 and 3). Since this is the same type of hydroxypropyl cellulose utilized in the instant application (paragraph [0040]), it necessarily has the same properties (i.e. the viscosity of a 2% aqueous solution is below 3.0 mPa•s at 20 °C). Since both Chen *et al.* and Shimizu *et al.* are concerned with the production of improved pharmaceutical suspensions, and since Chen *et al.* teach hydroxypropyl cellulose, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute one known component (i.e. HPC-

SSL) for another (HPC) in the compositions of Chen *et al.*, to produce a suspension the desired viscosity, reading on instant claim 5.

Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen *et al.* and Shimizu *et al.* as applied to claims 1 and 5 above, and further in view of Chen *et al.* (U.S. Patent No. 6,267,985; Issued Jul. 31, 200) (hereinafter Chen 2001).

10. Regarding claims 12 and 16, it is noted that the alternative language used for elements (i)-(v) requires only one of these elements to be satisfied. Chen *et al.* and Shimizu *et al.* teach the dry syrup preparation of instant claim 5, in which HPC-SSL is used as the binder component. Because the HPC-SSL is the critical component for the dispersibility of the formulation (paragraph [0021] of the instant specification), it is the examiner's position that many or all of the limiting elements of instant claims 12 and 16 would be satisfied by these compositions. However, Chen 2001 disclose pharmaceutical compositions containing loratadine and teach that these may be dispersions that appear cloudy (column 30, line 24; column 31, line 67 to column 32, line 3; column 38, lines 12-42). Although elements (ii) and (iii) further recite 5 g of the preparation which is upset, turned back, and left at rest, this limitation represents a design choice and values other than 5 g would exhibit this property as well. Nonetheless, given the teaching of the dry syrup preparation by Chen *et al.* and Shimizu *et al.*, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to formulate such preparations which would have met one or all of

elements (i)-(v) during the course of normal optimization to achieve a preparation of loratadine with improved dispersibility, reading on instant claims 12 and 16.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen *et al.* in view of Sriwongjanya *et al.* (U.S. Patent Application Publication No. 2003/0049319; Published Mar. 13, 2003) (hereinafter Sriwongjanya *et al.*) and Carceller *et al.* (U.S. Patent No. 5,407,941; Issued Apr. 18, 1995) (hereinafter Carceller *et al.*).

11. Chen *et al.* teach the dry syrup preparation of instant claims 1-4 as discussed above in paragraphs 1 and 2. While Chen *et al.* teach the use of loratadine, hydroxypropyl cellulose, sucrose, and colloidal silicon dioxide (i.e. silicon dioxide hydrate) (paragraph [0275]) in their formulations, they do not teach the use of these components in the claimed % weight ranges of instant claim 18.

12. Sriwongjanya *et al.* disclose pharmaceutical formulations for the administration of antihistamines including loratadine (abstract; Figure 3; paragraphs [0043] and [0051]). Sriwongjanya *et al.* teach the use of from 0.1-5% antihistamine (i.e. loratadine), 0.5-10% of a binder, which may be hydroxypropyl cellulose (paragraph [0030]), 0.1-5% of a lubricant, which may be silicon dioxide (paragraph [0032]), with the remaining weight of the formulation consisting of a matrix core that may include sucrose (paragraph [0031]; see paragraph [0037] and the table therein). Sriwongjanya *et al.* do not teach sucrose in the weight % range of 90.0-98.75%.

13. Carceller *et al.* disclose pharmaceutical compositions containing antihistamines that are loratadine analogues (abstract; structures in column 2, especially compound 4).

These compositions may take a number of forms including syrups (column 13 table, lines 15-20). In this embodiment sucrose is present in 98.4% by weight (using the dry components of the syrup per the definition of a dry syrup in the instant application) and the loratadine analogue (compound 4) is present at approximately 0.9%.

14. Since Chen *et al.,* Sriwongjanya *et al.*, and Carceller *et al.* are each concerned with the production of pharmaceutical formulations containing antihistamines (loratadine and its analogues), it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to incorporate each of these known components into the dry syrup formulations of Chen *et al.* based on the percent weight ranges taught in the art to achieve a formulation with the desired organoleptic and physical properties, reading on instant claim 18.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

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